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| APPLICATION NO.        | FILING DATE                             | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------|---|----------------------|---------------------|------------------|
| 10/734,762             | 12/11/2003                              | John B. Enns         | VTN 568 CIP3        | 1967             |
| 27777<br>PHILIP S. JOH | 7590 09/03/200<br><b>NSON</b>           | EXAMINER             |                     |                  |
| JOHNSON & J            | OHNSON                                  | WEBB, WALTER E       |                     |                  |
|                        | N & JOHNSON PLAZ<br>VICK, NJ 08933-7003 |                      | ART UNIT            | PAPER NUMBER     |
|                        |   |                      | 1612                |                  |
|                        |   |                      |                     |                  |
|                        |   |                      | MAIL DATE           | DELIVERY MODE    |
|                        |   |                      | 09/03/2008          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|  |  | Applicat  | Application No.   |  | Applicant(s) |  |  |
|--|--|---|---|--|--------------|--|--|
| Office Action Summary  |  | 10/734,7  | 762   | ENNS ET AL.  |              |  |  |
|  |  | Examine   | er  | Art Unit   |              |  |  |
|  |  | WALTER  | R E. WEBB   | 1612   |              |  |  |
| Period fo  | The MAILING DATE of this communic<br>r Reply   | cation appears on th  | ne cover sheet wit  | h the correspondence a   | ddress       |  |  |
| A SHO WHIC - Exter after - If NO - Failur Any r  | DRTENED STATUTORY PERIOD FO<br>HEVER IS LONGER, FROM THE MA<br>sions of time may be available under the provisions of<br>SIX (6) MONTHS from the mailing date of this commu-<br>period for reply is specified above, the maximum state<br>to reply within the set or extended period for reply we<br>eply received by the Office later than three months afted<br>patent term adjustment. See 37 CFR 1.704(b). | ALLING DATE OF T<br>f 37 CFR 1.136(a). In no e<br>inication.<br>utory period will apply and v<br>vill, by statute, cause the ap | THIS COMMUNIC<br>event, however, may a re<br>will expire SIX (6) MONT<br>oplication to become ABA | CATION.  ply be timely filed  THS from the mailing date of this ANDONED (35 U.S.C. § 133). |              |  |  |
| Status   |  |   |   |  |              |  |  |
| 1)⊠<br>2a)⊠  | Responsive to communication(s) filed This action is <b>FINAL</b> . 2 Since this application is in condition for closed in accordance with the practic  | b)∏ This action is<br>or allowance excep  | ot for formal matte   | •  | ne merits is |  |  |
| Dispositi  | on of Claims   |   |   |  |              |  |  |
| 5)□<br>6)⊠<br>7)□<br>8)□<br><b>Applicati</b><br>9)□  | Claim(s) 1-22 and 24-35 is/are pending 4a) Of the above claim(s) is/are claim(s) is/are allowed.  Claim(s) 1-22 and 24-35 is/are rejected to.  Claim(s) is/are objected to.  Claim(s) are subject to restrict  on Papers  The specification is objected to by the The drawing(s) filed on is/are:  | e withdrawn from or ed.  ion and/or election  Examiner.   | onsideration.<br>requirement.   | oy the Examiner.   |              |  |  |
| <ul> <li>10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).</li> <li>11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.</li> </ul>  |  |   |   |  |              |  |  |
| Priority u   | nder 35 U.S.C. § 119   |   |   |  |              |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul> |  |   |   |  |              |  |  |
| 2)  Notice 3)  Inform  | e of References Cited (PTO-892)<br>e of Draftsperson's Patent Drawing Review (PT<br>nation Disclosure Statement(s) (PTO/SB/08)<br>No(s)/Mail Date <u>7/23/2008, 2/21/2008</u> .  | <sup>-</sup> O-948)   | Paper No(s)   | ummary (PTO-413)<br>)/Mail Date<br>formal Patent Application<br>_·                         |              |  |  |

## **DETAILED ACTION**

Applicants' arguments, filed 5/30/2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

## Claim Rejections - 35 USC § 103

The rejection of claims 1-22 and 24-35 as being unpatentable over Lai in view of Nochumson, Monestere, and Rudnick is maintained.

Applicant argues that there is nothing in Lai et al., Monestere or Nochumson that would suggest than any monomer could be incorporated into a lens formulation and used as a ligand monomer to reversibley bind silver. However, the motivation to provide N,N'-bisacylylcystamine as the monomer for Lai et al. stems from the fact that Lai et al. teaches incorporating divinyl monomers as crosslinking agents and N,N'-bisacylylcystamine is divinyl monomer known in the art as a crosslinking agent, as evidenced by Nochumson. Applicant's claims do not require that the monomer reversibly bind silver. This requirement argued by applicant is not commensurate in scope with the claimed invention.

Applicant argues that Monostere does not suggest that silver could be associated with the lens by any means other than precipitation. However, as applicant points out, the silver nitrate of Monostere penetrates and becomes part of the lens, which is, therefore, an association with the lens other than precipitation.

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Applicant also argues that none of the references disclose an antimicrobial lens. However, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. The references taken as a whole reasonably suggest antimicrobial lenses, since they teach incorporation of silver nitrate, which would necessarily render the lenses antimicrobial.

Applicant also argues that there is no suggestion to cure a reaction mixture containing the ligand monomer under reaction conditions "sufficient to provide a reactivity ratio of the ligand monomer to at least one major lens forming component of at least about 0.45 lens. However, curing the lens to where the ratio of ligand monomer (N,N'-bisacylylcystamine) to one major lens forming component is merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. For example, Lai et al. teach adding crosslinking agents, i.e. N,N'-bisacylylcystamine in a range of 0.01 to about 10 wt% and curing the monomeric mixture with polymerization initiators, where the initiators are at a concentration of about 0.001 to 2 percent. (See col.5, lines 22-24, and lines 26-35.) The artisan could add the crosslinking agent at 0.1% and add the initiator at 0.22%, which would yield a ratio of about 0.45.

Applicant also argues surprising results based on examples 4-10 of the specification. They state that silver is not incorporated at the desired amounts without the appropriate reactivity ratio. However, the discussion of Table 2 of examples 4-10 at page 32 does not mention reactivity ratios. It shows that incorporation of silver nitrate into the lens is complete when the initiator is at a concentration of 1.35 ppm, and that

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incorporation of silver nitrate is incomplete 61.9% to 72.9% when the initiator is at a low or intermediate concentration. Applicant does not specifically claim an initiator concentration of 1.35ppm. Instead, applicant claims the initiator concentration at about 0.4%, 0.9% and about 0.4 to about 2% (claims 32-35). Since Lai et al. teach adding the initiator in the same relative proportions, i.e. 2%, once the silver nitrate is sprayed on the lens as described in Monestere, the lens would inherently incorporate the desired amounts of silver.

## Nonstatutory Obvious-type Double Patenting

1) The provisional rejection of claims 1, 7-8, 13, 15, 19 and 21 as being unpatentable over claims 9 and 23-24 of copending application 10/715,745 is maintained.

Applicant argues that Rathore does not disclose or suggest cure conditions which provide the reactivity ratios recited in the present application, or the cure intensity which is an important factor in achieving the reactivity ratio. However, determining reactivity ratio would be inherent to the incorporation of the silver as the antimicrobial agent with the ligand. Therefore, determining the reactivity is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

2) The provisional rejection of claims 1, 7-8, 13, 15, 19 and 21 as being unpatentable over claims 1, 10, 11 and 17 of copending application 10/719,903 is maintained.

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Applicant argues that Anderson does not disclose a ligand monomers which reversibly bind silver and reactivity ratios. However, the same ligands are claimed insofar as formula IV of the instant claim 1 and formula I of the '903 application are the same. Determining reactivity ratio would be inherent to the incorporation of the silver as the antimicrobial agent with the ligand. Therefore, determining the reactivity is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

## Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Walter E. Webb/ /Walter E Webb/ Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612